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# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

STEPHANIE CLARK, Plaintiff,

VS.

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA LP

Defendants.

DEFENDANTS' MOTION TO DISMISS

Case 1:16-cv-00160 DAK

Judge Dale A. Kimball

Pursuant to Rules 12(b)(6), 8(a)(2), and 9(b), Defendants AstraZeneca Pharmaceuticals, LP and AstraZeneca, LP (collectively, "AstraZeneca"), hereby move to dismiss Plaintiff's Complaint.

#### **INTRODUCTION**

Plaintiff Stephanie Clark<sup>1</sup> ("Plaintiff") filed a Complaint against AstraZeneca alleging that her ingestion of "Nexium and/or other Nexium branded products" caused her to develop "acute kidney injury" and "acute interstitial nephritis" in 2006.<sup>2</sup> Plaintiff asserts twelve causes of action, most of which are largely overlapping.<sup>3</sup> Plaintiff's Complaint fails to state a claim upon which relief can be granted for the following reasons:

- 1. Plaintiff's claims are barred by the applicable statute of limitations.
- 2. Prescription drug manufacturers are exempt from liability for design defects and for failure to warn consumers directly about the risks of prescription medications.
- 3. Plaintiff has otherwise failed to satisfy the pleading standards of Rule 8(a)(2) or Rule 9(b) of the Federal Rules of Civil Procedure.

For these reasons and those set forth below, AstraZeneca respectfully requests dismissal with prejudice of the Complaint in its entirety.

<sup>&</sup>lt;sup>1</sup> The caption and introductory paragraph of the Complaint refer to Plaintiff as "Stephanie Clark," but paragraphs 48-51, 54-55 spell her last name "Clarke." *See* Dkt. 2.

<sup>&</sup>lt;sup>2</sup> See Dkt. 2 at  $\P$  1.

<sup>&</sup>lt;sup>3</sup> The causes of action are: (1) "Strict Product Liability," (2) "Strict Product Liability (Pursuant to Restatement Second of Torts 402a (1965)," (3) "Intentional Infliction of Emotional Distress," (4) "Negligent Infliction of Emotional Distress," (5) "Common Law Fraud," (6) "Negligence," (7) "Negligent Misrepresentation," (8) "Fraudulent Misrepresentation," (9) "Express Warranty," (10) "Implied Warranty," (11) "Warranty of Merchantability," and (12) "Warranty of Fitness." *See generally* Dkt. 2.

#### ARGUMENT

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, an action should be dismissed if the plaintiff has "fail[ed] to state a claim upon which relief can be granted." Here, Plaintiff's claims should be dismissed because they are time-barred and because Plaintiff has offered nothing more than legal conclusions masquerading as factual allegations.

#### I. PLAINTIFF'S CLAIMS ARE TIME-BARRED.

The Utah Product Liability Act ("UPLA") establishes a two-year limitations period for all claims alleging a defective product:

A civil action under this part shall be brought within two years from the time the individual who would be the claimant in the action discovered, or in the exercise of due diligence should have discovered, both the harm and its cause.<sup>4</sup>

This two-year limitations period applies to all product liability cases, whether based in strict liability, negligence, or any other legal theory. *See Utah Local Gov't Trust v. Wheeler Machinery Co.*, 199 P.3d 949, 951 (Utah 2008) (The UPLA statute of limitations "encompasses all actions seeking money damages for injury to people or property resulting from defective products."). Thus, this two-year limitations period applies to and bars all of Plaintiff's claims in this action.<sup>5</sup>

<sup>&</sup>lt;sup>4</sup> Utah Code § 78B-6-706.

<sup>&</sup>lt;sup>5</sup> Even Plaintiff's fraud claims are governed by the UPLA's two-year statute of limitations because "[t]he fraud statute of limitations is [] far broader than the [UPLA], and our rules of statutory construction provide that the more specific . . . act applies instead of the more general fraud statute of limitations." *Jensen v. IHC Hosps., Inc.*, 944 P.2d 327, 335 (Utah 1997), on reh'g (Aug. 22, 1997) (holding that the two-year medical malpractice statute of limitations applied to fraud claims related to alleged medical malpractice.") Given the nature of Plaintiff's claims, which sound in products liability, Plaintiff's claims of fraud, fraudulent misrepresentation, negligent misrepresentation and fraudulent concealment should be considered within the context of UPLA's statutory discovery rule. In any event, Plaintiff's claims would

The UPLA includes a "statutory discovery rule," meaning that the statute, by its own terms, does not allow the limitations period to commence until a would-be plaintiff discovers or should have discovered a cause of action. *See Russell Packard Dev., Inc. v. Carson*, 2005 UT 14, ¶ 21, 108 P.3d 741 (explaining the concept of a "statutory discovery rule"); *Aragon v. Clover Club Foods Co.*, 857 P.2d 250, 252 (Utah Ct. App. 1993) (observing that the UPLA incorporates its own discovery rule). Specifically, the two-year limitations period under the UPLA begins to run once a would-be plaintiff has "discovered, or in the exercise of due diligence should have discovered, both the harm and its cause."

Here, Plaintiff discovered "the harm" when she was diagnosed with two kidney disorders on July 15, 2006 and December 12, 2006.<sup>7</sup> The two-year statute of limitations arguably began to run upon these diagnoses in 2006, and since Plaintiff failed to file suit until more than two years from December 12, 2006, her claims are barred.

To overcome this result, Plaintiff alleges in her Complaint that the statute of limitations was tolled until she actually discovered "the cause" of her kidney disorders through "recent studies published in medical journals." Plaintiff's position reflects an incorrect understanding of Utah law, which requires that Plaintiff bring an action within two years of when "in the

still be time-barred under the three-year statute of limitations for fraud. *See* Utah Code § 78B-2-305(3).

<sup>&</sup>lt;sup>6</sup> Utah Code § 78B-6-706.

<sup>&</sup>lt;sup>7</sup> Dkt. 2 at ¶¶ 52-53.

 $<sup>^{8}</sup>$  *Id.* at ¶ 61.

exercise of due diligence[, she] should have discovered" the "cause." As such, Plaintiff has failed to adequately plead that the statute should be tolled. 10

Plaintiff attempts to overcome the bar of her suit by claiming, without supporting allegations, that AstraZeneca somehow fraudulently concealed the dangers of its product. *See Russell Packard Dev., Inc. v. Carson*, 2005 UT 14, ¶¶ 37-38, 108 P.3d 741 (recognizing that a plaintiff alleging tolling of the statute of limitations based on fraudulent concealment by the defendant has the burden to "ma[k]e a prima facie showing of fraudulent concealment"). Not only has Plaintiff failed to meet that pleading burden, but at this stage of the case, Plaintiff pleads no facts to establish that she exercised due diligence in identifying the "cause" of her kidney disorder. Nor does she plead any facts to explain how AstraZeneca somehow concealed any risks associated with Nexium or how AstraZeneca's actions affected Plaintiff's ability to discover the cause of her kidney disorders. Her allegation that her delayed discovery was due to AstraZeneca's fraudulent concealment is speculative and conclusory and fails to meet the heightened pleading standards of Rule 9(b) of the Rules of Civil Procedure. *See Section II.B, infra.* 

Plaintiff has not met her burden to establish the tolling of the statute of limitations. Therefore, because her claims are time-barred under the UPLA, her action should be dismissed with prejudice in its entirety.

<sup>&</sup>lt;sup>9</sup> Utah Code § 78B-6-706.

<sup>&</sup>lt;sup>10</sup> Also at trial Plaintiff bears the burden of proof on this issue.

<sup>&</sup>lt;sup>11</sup> Dkt. 2 at ¶¶ 56-61.

<sup>&</sup>lt;sup>12</sup> *Id.* at ¶ 60 ("Any applicable statute of limitations has therefore been tolled by Defendants' knowledge, active concealment and denial of the facts alleged herein, which behavior is ongoing.").

#### II. PLAINTIFF HAS FAILED TO STATE A CLAIM UNDER RULE 8.

Rule 8(a)(2) of the Federal Rules of Procedure requires not only "a short and plain statement of the claim" but also one that "show[s] that the pleader is entitled to relief." Thus, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

The Tenth Circuit has identified two principles to flesh out this plausibility standard. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Burnett v. Mortg. Elec. Registration Sys., Inc.*, 706 F.3d 1231, 1235–36 (10th Cir. 2013) (quoting *Iqbal*, 556 U.S. at 678). "Thus, mere 'labels and conclusions,' and 'a formulaic recitation of the elements of a cause of action' will not suffice." *Kan. Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1214 (10th Cir.2011) (quoting *Twombly*, 550 U.S. at 555); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 679, 129 S. Ct. 1937, 1950, 173 L. Ed. 2d 868 (2009) (applying *Twombly* and noting that Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions").

Second, "a plaintiff must offer specific factual allegations to support each claim." *Id.* The Court must compare "the pleading with the elements of the cause(s) of action" to determine whether those elements are substantiated with factual allegations. *Id.* (internal citations omitted). This is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *McCartney v. United States*, 31 F. Supp. 3d 1340, 1343 (D. Utah 2014).

# A. The Complaint Does Not State a Claim for Strict Product Liability.

The elements of a strict product liability claim in Utah are, "(1) that a *defect* or defective condition of the product made it unreasonably dangerous, (2) that the defect was present at the time of the product's sale, and (3) that the defective condition was the *cause* of the plaintiff's injuries." *Gudmundson v. Del Ozone*, 2010 UT 33, ¶ 53, 232 P.3d 1059 (internal citations omitted) (emphasis added). Under Utah law, "[t]here are three types of product defects: manufacturing flaws, design defects, and inadequate warnings regarding use." *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991).

## 1. Plaintiff Cannot State a Claim for Design Defect.

Plaintiff's claim that the Nexium manufactured by AstraZeneca was "defective in design or formulation" (Count 2) cannot be maintained under Utah law. The Utah Supreme Court expressly held in *Grundberg* that a strict product liability claim for design defect cannot be maintained against a prescription drug manufacturer. Specifically, the Court held that "a broad grant of immunity from strict liability claims based on design defects should be extended to FDA-approved prescription drugs in Utah." *Grundberg*, 813 P.2d at 99. The Court based its ruling on "the strong public interest in the availability and affordability of prescription medications" and "the extensive regulatory system of the FDA." *Id.* Because prescription Nexium was approved by the FDA and must be prescribed by a physician, under Utah law, AstraZeneca is granted broad immunity from any strict liability claim based on the theory of

 $<sup>^{13}</sup>$  See Dkt. 2 at  $\P$  67 (Count 2).

design defect. Accordingly, Plaintiff's strict liability claim for design defect (Count 2) should be dismissed as a matter of law.

2. Plaintiff Cannot State a Claim for Failure to Warn.

Plaintiff claims that AstraZeneca is strictly liable for failing to provide adequate warnings regarding the alleged risk of kidney injuries, "including, but not necessarily limited to, long term usage and the cumulative effects of long term usage" of Nexium.<sup>14</sup>

If Plaintiff ingested only prescription brand Nexium, her claim that AstraZeneca failed to warn her of the risks is barred by the learned intermediary doctrine. *See Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 2003 UT 43, ¶ 20, 79 P.3d 922. Under the learned intermediary doctrine,

manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, *not the end user or patient*.

Id. (Emphasis added). The contours of this duty include making "timely and adequate warnings to the medical profession of any dangerous side effects produced by its drug of which it knows or has reason to know." Id. (citing Barson v. E.R. Squibb & Sons, 682 P.2d 832, 835 (Utah 1984)). "The physician, after having received complete and appropriate warnings from the drug manufacturer, acts as a learned intermediary between the drug manufacturer and the patient when preparing the drug prescription." Schaerrer, 2003 UT 43, ¶ 20 (emphasis in original). Therefore, a drug manufacturer's duty is to give timely, adequate, complete, and appropriate warnings to the prescribing physician—not to the physician's patient. See id.

The allegations of Count 1 of Plaintiff's Complaint ("Strict Liability") focus on warnings that Plaintiff claims AstraZeneca failed to make to her as the consumer. Plaintiff makes no

<sup>&</sup>lt;sup>14</sup> *Id.* at ¶ 28.

mention of her physicians in her claim for strict liability failure to warn (Count 1). To the extent the Court may consider allegations in other Counts of the Complaint, e.g., Count 6 "Negligence," regarding failure to warn, Plaintiff has alleged no facts to substantiate her conclusory allegation that AstraZeneca failed to provide adequate warnings to the physicians (if any) who wrote her prescriptions for Nexium. Plaintiff's Complaint is devoid of any factual allegations showing that the warnings AstraZeneca provided to physicians were deficient, whether Plaintiff's own physicians were aware of the risks associated with prescription Nexium, or whether Plaintiff's own physicians may have failed to communicate those risks to Plaintiff. Because AstraZeneca, as a prescription drug manufacturer, owed no duty to warn consumers of the risks of prescription Nexium, Plaintiff's claim that AstraZeneca failed to provide adequate warnings directly to her cannot be maintained under Utah law. Plaintiff's strict liability failure to warn claim should therefore be dismissed.

This is not a situation where Plaintiff is unable to plead facts sufficient to "nudge [her] claims across the line from the conceivable to the plausible" because all of the relevant facts are in the possession of the defendant. *See Twombly*, 550 U.S. at 569. At a minimum, Plaintiff should be able to identify what warnings were received, who received them, how they were deficient, and how the deficient warnings caused harm to her. Plaintiff has failed to adequately plead facts to show that AstraZeneca failed to provide appropriate warnings to her physicians.

#### 3. Plaintiff Has Not Adequately Pled Causation.

Plaintiff's Complaint also fails to plausibly plead the third element of a strict product liability claim – "that the defective condition [or failure to warn] was the *cause* of the plaintiff's injuries." *Gudmundson*, 2010 UT 33, ¶ 53 (emphasis added). Under Utah law, "[b]efore a

manufacturer may be held liable for a failure to warn, that failure must be both the cause-in-fact and the proximate cause of the user's injury." *Kirkbride v. Terex USA, LLC*, 798 F.3d 1343, 1349 (10<sup>th</sup> Cir. 2015) (quoting *House v. Armour of Am., Inc.*, 886 P.2d 542, 551 (Utah Ct. App. 1994)).

The Complaint's sole assertion about causation is merely a legal conclusion: "The injuries and damages sustained by Plaintiff, Stephanie Clarke, were caused by Defendants' Nexium product." Federal courts are "not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678; *see also Kansas Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1214 (10th Cir. 2011) ("Thus, in ruling on a motion to dismiss, a court should disregard all conclusory statements of law and consider whether the remaining specific factual allegations, if assumed to be true, plausibly suggest the defendant is liable"). Plaintiff's Complaint contains no allegations explaining *how* her use of Nexium was the cause-in-fact or proximate cause of her kidney issues. She does not point to any determination by a physician, other medical authority, or expert pointing to Nexium as the cause of her kidney issues.

Plaintiff has not pled sufficient factual allegations to support a claim that AstraZeneca's prescription form of Nexium was both the cause-in-fact and the proximate cause of her alleged kidney injuries. For this additional reason, her strict-liability claims (and other claims as identified below) should be dismissed.

<sup>&</sup>lt;sup>15</sup> *Id.* at ¶ 55.

# B. The Complaint Does Not State a Claim for Common Law Fraud, Fraudulent Misrepresentation, or Negligent Misrepresentation.

Rule 9(b) provides that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed.R.Civ.P. 9. Thus, allegations of fraud must meet a higher standard than the basic notice pleading required by Rule 8.

At a minimum, Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud and must set forth the time, place, and contents of the false representation, the identity of the party making the false statements and the consequences thereof.

U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, 472 F.3d 702, 726–27 (10th Cir. 2006) (quoting Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997) and Koch v. Koch Indus., 203 F.3d 1202, 1236 (10th Cir. 2000) (internal quotation marks omitted).

Here, Plaintiff asserts three fraud allegations. The first two, "Common Law Fraud" and "Fraudulent Misrepresentation," are proved by the same elements:

(1) that a representation was made (2) concerning a presently existing material fact (3) which was false and (4) which the representor either (a) knew to be false or (b) made recklessly, knowing that there was insufficient knowledge upon which to base such a representation, (5) for the purpose of inducing the other party to act upon it and (6) that the other party, acting reasonably and in ignorance of its falsity, (7) did in fact rely upon it (8) and was thereby induced to act (9) to that party's injury and damage.

State v. Apotex Corp., 2012 UT 36, ¶ 58, 282 P.3d 66, 80 (reciting the elements for fraudulent misrepresentation); Armed Forces Ins. Exch. v. Harrison, 2003 UT 14, ¶ 16, 70 P.3d 35, 40 (reciting the elements for "a claim sounding in fraud"). The elements Plaintiff must allege to

<sup>&</sup>lt;sup>16</sup> *Id.* at ¶¶ 85-88 and ¶¶ 95-97.

support her third fraud claim, negligent misrepresentation, <sup>17</sup> are similar to those of fraud except that negligent misrepresentation 'does not require the intentional mental state necessary to establish fraud." *Price-Orem Inv. Co. v. Rollins, Brown & Gunnell, Inc.*, 713 P.2d 55, 59 n. 2 (Utah 1986). Therefore, Plaintiff must allege facts supporting each of the following elements to state a claim for negligent misrepresentation: "(1) a party carelessly or negligently makes a false representation 'expecting the other party to rely and act thereon,' (2) the plaintiff actually relies on the statement, and (3) suffers a loss as a result of that reliance." *Moore v. Smith*, 2007 UT App 101, ¶36, 158 P.3d 562 (quoting *Smith v. Frandsen*, 2004 UT 55, ¶ 9, 94 P.3d 919). The allegations of the Complaint fail to allege facts in support of these allegations under the Rule 8(a)(2) standard set forth above, much less under the more rigorous standard of Rule 9(b), which requires the circumstances of fraud to be set forth with particularity.

Plaintiff supports her claim for "Fraudulent Misrepresentation" with the following conclusory statement,

By their advertising, labels, or otherwise, Defendants have made a misrepresentation of a material fact concerning the character or quality of Nexium to Plaintiff and the public.<sup>18</sup>

This statement is nothing more than a legal conclusion and should not be presumed true. *See Burnett*, 706 F.3d at 1235–36 (stating that legal conclusions in a complaint should not be

While it may not be self-evident that "negligent misrepresentation" is a fraud claim, "Utah cases have acknowledged that 'negligent misrepresentation is a form of fraud." *Smith v. Frandsen*, 2004 UT 55, ¶ 11, 94 P.3d 919 (quoting *Atkinson v. IHC Hosps., Inc.*, 798 P.2d 733, 737 (Utah 1990); citing *Christenson v. Commonwealth Land Title Co.*, 666 P.2d 302, 305 (Utah 1983) ("Negligent misrepresentation is a tort which grew out of common-law fraud.") and *Robinson v. Tripco Inv., Inc.*, 2000 UT App 200, ¶ 31, 21 P.3d 219 (Billings, J., dissenting) (identifying negligent misrepresentation as a "species" of fraud).)

18 Dkt. 2 at ¶ 96.

accepted as true when considering a motion to dismiss). In support of her claim for "Common Law Fraud," Plaintiff alleges generally that AstraZeneca made misrepresentations regarding the efficacy, risks, and adverse events associated with Nexium. These alleged misstatements are not identified with particularity, are described only in the most general terms, and wholly fail to "set forth the time, place, and contents of the false representation, the identity of the party making the false statements and the consequences thereof," as required by Rule 9(b). *U.S. ex rel. Sikkenga*, 472 F.3d at 726–27. For example, Plaintiff fails to identify any misrepresentations in any particular advertising, labels, or other publications. She also fails to allege facts suggesting that AstraZeneca knew or should have known any particular representations to be false at the time they were made. *See Harrison*, 2003 UT 14, ¶ 16 (reciting the elements for "a claim sounding in fraud"). Plaintiff cannot transform a failure-to-warn claim into a fraud claim by merely labeling the failure to warn as "fraudulent." She must plead "with particularity" "the circumstances constituting fraud." *See* Fed.R.Civ.P. 9(b). This she has failed to do.

It appears that Plaintiff's intent is to paint her fraud allegations with a broad brushstroke and then engage in wide-ranging discovery in the hope of discovering facts that might substantiate her fraud claims. This is precisely the type of opportunism that Rule 9(b) is designed to prevent. *See In re Grand Casinos, Inc. Sec. Litig.*, 988 F. Supp. 1273, 1281 (D. Minn. 1997) (explaining Rule 9(b)'s purpose of deterring "fishing expeditions of unknown wrongs designed to compel 'in terrorem settlements'"). Plaintiff's fraud allegations fall woefully short of the heightened requirements for pleading fraud established in Rule 9(b). They also fail due to her failure to plead causation. *See Section II.A.3, supra.* These claims should therefore be dismissed as a matter of law.

# C. The Complaint Does Not State a Claim for Intentional or Negligent Infliction of Emotional Distress.

To succeed on a claim of intentional infliction of emotional distress, a plaintiff in Utah must demonstrate that the defendant

intentionally engaged in some conduct toward the plaintiff, (a) with the purpose of inflicting emotional distress, or, (b) where any reasonable person would have known that such would result; and his actions are of such a nature as to be considered outrageous and intolerable in that they offend against the generally accepted standards of decency and morality.

Cabaness v. Thomas, 2010 UT 23, ¶ 36, 232 P.3d 486 (internal citations omitted). To succeed on a claim of negligent infliction of emotional distress, a plaintiff in Utah must demonstrate that

(1) the defendant unintentionally caused emotional distress to the plaintiff; (2) the defendant should have realized that his conduct involved an unreasonable risk of causing the distress, otherwise than by knowledge of the harm or peril of a third person; (3) the defendant, from facts known to him, should have realized that the distress, if it were caused, might result in illness or bodily harm; and (4) the emotional distress resulted in illness or bodily harm to the plaintiff.

Candelaria v. CB Richard Ellis, 2014 UT App 1, ¶ 9, 319 P.3d 708 (internal citations omitted). Here, Plaintiff has not alleged facts to make any of the elements of either cause of action plausible.

With regard to the claim for intentional infliction of emotional distress, Plaintiff has not alleged facts showing that AstraZeneca intended to cause her emotional distress or should have known that such would result. *See Cabaness*, 2010 UT 23, ¶ 36. Nor has she alleged conduct that is "outrageous and intolerable" or that offends "standards of decency and morality." *See id.* The allegations about AstraZeneca's behavior asserted by Plaintiff in support of her claim for intentional infliction of emotional distress qualify as nothing more than legal conclusions, which this Court should not presume are true for purposes of this motion. *See Burnett*, 706 F.3d at

1235–36 (stating that legal conclusions in a complaint should not be accepted as true when considering a motion to dismiss).

With regard to the claim for negligent infliction of emotional distress, Plaintiff has most notably failed to plead that any emotional distress "resulted in illness or bodily harm" as required by Utah law. *See Candelaria*, 2014 UT App 1, ¶ 9. She has also failed to plead facts suggesting that AstraZeneca should have known its actions would result in emotional distress to plaintiff or that such emotional distress might result in illness or bodily harm. *See id.* Both of Plaintiff's infliction of emotional distress claims should therefore be dismissed. *See Burnett*, 706 F.3d at 1235–36 (quoting *Iqbal*, 556 U.S. at 678) (A plaintiff must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.").

### D. The Complaint Does Not State a Claim for Negligence.

Under Utah law, a negligence claim has four elements:

(1) that the defendant owed the plaintiff a duty, (2) that the defendant breached that duty, (3) that the breach of duty was the proximate cause of the plaintiff's injury, and (4) that the plaintiff in fact suffered injuries or damages.

Gonzalez v. Russell Sorensen Const., 2012 UT App 154, ¶ 20, 279 P.3d 422. Plaintiff's negligence claim should be dismissed for the same reasons that her strict liability claims should be dismissed. Under Utah law, prescription drug manufacturers are exempt from liability for design defects and for failure to warn consumers of the risks of prescription drugs. See Section II.A.1, supra. Plaintiff has presented no factual averments for a negligence claim based on failure to warn or any other acts or omissions. See Section II.A.2, supra. The negligence claim

 $<sup>^{19}</sup>$  *Id.* at ¶¶ 89-91.

also fails due to Plaintiff's failure to plead causation. *See Section II.A.3, supra*. The negligence claim should therefore be dismissed.

### E. The Complaint Does Not State a Claim for Express or Implied Warranty.

Plaintiff asserts causes of action for Express Warranty,<sup>20</sup> Implied Warranty,<sup>21</sup> Warranty of Merchantability (a type of implied warranty),<sup>22</sup> and Warranty of Fitness (another type of implied warranty).<sup>23</sup> Under Utah law, "The elements of strict liability and breach of warranty are essentially the same." *Straub v. Fisher & Paykel Health Care*, 1999 UT 102, 990 P.2d 384 (internal citations omitted); *see also Davidson Lumber Sales, Inc. v. Bonneville Inv., Inc.*, 794 P.2d 11, 14 (Utah 1990) ("The term 'warranty' has also been used, however, in tort law to have a meaning that is synonymous with strict liability."). Therefore, these claims should be dismissed for the same reasons as the strict liability claims. *See* Section II.A, *supra*. In addition, the claim for Express Warranty should be dismissed because Plaintiff does not identify any express warranties made by AstraZeneca regarding Nexium.<sup>24</sup>

#### CONCLUSION

For the foregoing reasons, the Complaint should be dismissed with prejudice in its entirety.

 $<sup>^{20}</sup>$  *Id.* at ¶¶ 98-99.

<sup>&</sup>lt;sup>21</sup> See id. at ¶¶ 100-110.

 $<sup>^{22}</sup>$  *Id.* at ¶¶ 111-112.

 $<sup>^{23}</sup>$  *Id.* at ¶¶ 113-114.

 $<sup>^{24}</sup>$  See id. at ¶¶ 98-99.

# DATED this 16th day of May, 2017.

Respectfully submitted,

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